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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/960,557	10/31/1997	EUGENIO A. CEFALI	SD-50003USP6	6174

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
04/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents_Abbott_Park@abbott.com
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Office Action Summary	Application No.	Applicant(s)	
	08/960,557	CEFALI ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30,32,35,36,38,41,42,44,62 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30,32,35,36,38,41,42,44,62 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and remarks dated 12-29-08 is acknowledged.

Status of Claims

Claims 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 are pending.

In response to the amendment to claim 29, the following rejection has been withdrawn:

Claim Rejections - 35 USC § 112

1. Claims 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A review of the instant specification on pages 6, lines 21-25, page 20, lines 3-16 and table II on page31 reveals that the instant claim limitations "for achieving a balanced lipid alteration in a patient in need thereof", "at least two formulations comprising" are not supported by the instant specification with respect to 500 mg and 1000 mg. In other words, while the new claim limitations are supported with at least two 750 mg formulations to achieve a daily dose of 1500 mg, the specification (at the above cited places) do not appear to support the at least two with respect to 500 mg and 1000 mg to achieve a daily dose of 1500 mg. Specifically, on page 20 of the specification it is stated that two tablets of 500 mg for a 1000 mg dose, two tables of 750 mg for 1500 mg dose and 2 tablets of 1000 mg for a 2000 mg dose, which is not the same as that

claimed i.e., "at least two intermediate release formulations comprising 500, 750 or 1000 mg of nicotinic acid and a swelling agent to obtain a dose of at least 1500 mg". Further, the at least two tablet limitation on page 20 does not appear to be associated with the claimed "for achieving a balanced lipid alteration in a patient in need thereof". Hence, the claims lack written description support.

2. In response to that amendment, the rejections previously of record have been withdrawn and the following new rejection has been applied to the pending claims:

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5260305 to Dennick in view of either Saito et al (Arteriosclerosis and Thrombosis, 1991) or US 511610 to Broaddus ('610) and Saito et al (Arteriosclerosis and Thrombosis, 1991).

5. Dennick teaches a combination of cholesterol lowering drugs that include niacin, of the instant claims, for effectively lowering cholesterol levels, such as LDL and for treating hyperlipiemia (col. 2). Dennick teaches niacin in an amount ranging 75 mg to 2000 mg (col. 3, L 49-63), in a single or divided dosage forms. For the claimed swellable polymers, Dennick gelatin, starch etc (col. 4, L 37-40). While Dennick does not state 1500 mg in a single dose, the range of 75 -2000mg includes the claimed 1500 mg because Dennick teaches starting with a low dose and working up to higher

concentrations so as to achieve a desired effect (col. 3, l 64-67). Thus, administering a dose of 1500 mg would have been within the scope of a skilled artisan with an expectation to achieve the desired treatment for elevated cholesterol levels. Dennick fails to teach administering at evening or night.

6. '610 teach an oral composition comprising cholestyramine and polyol polyesters for reduced cholesterol levels and in the treatment of hypercholesterolemia (col. 2). '610 teach the compounds in the form of tablets (col. 2). For the treatment, '610 suggests that administering the drug at evening before meals or bed time is preferred (col. 6, L 18-20) for effective reduction in cholesterol levels.

7. Saito et al studied a comparison between morning and evening doses of simvastatin in hyperlipidemic subjects and observed that once-a-day evening oral doses of simvastatin reduced cholesterol levels in the subjects greater than when the drug was given in the morning (abstract, pages 825). Saito states that there is circadian variation in the biosynthesis of cholesterol and that the biosynthesis activity is accelerated at night (lines bridging pages 816-817).

8. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to administer the niacin composition of Dennick at evening or night suggested by '610 or Saito because both references suggest administering at evening or bed time is safe and effective and further Saito teaches that due circadian rhythms the cholesterol biosynthesis is more at night and therefore administering when at the time when the cholesterol synthesis is high is effective in reducing cholesterol levels and thus controlling the levels of serum cholesterol (page 824, col. 1). Thus, a skilled

artisan would have expected to achieve the balance of cholesterol levels without any associated side effects such as hepatotoxicity and yet a prolonged release of niacin in the composition of Dennick.

Response to Arguments

9. Applicant's arguments with respect to claim 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 have been considered but are moot in view of the new ground(s) of rejection. Applicants did not specifically argue the teachings of Dennick.

Terminal Disclaimer

10.

11. The terminal disclaimer filed on 4-8-08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,080,428, 6,129,930, 6,469,035, 6,406,715, 6,746,691, 6,818,229 and 7,011,848 and application no. 10/444,145 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner,
Art Unit 1611
March 29, 2009